

[Document Name]
[Project Name]

[Document Name]
[Section Number]

5 Non-Functional Requirements

Non-functional requirements specify the requirements not covered by the functional requirements. They specify criteria that judge the operation of a system, rather than specific behaviors. Typical non-functional requirements include Availability, Performance, Response Time, and Throughput.

5.1.1 Accuracy

Describe the accuracy requirements to be imposed on the system.

[Req #]	Title
Req #	The software shall...
Req #	The software shall...
Req #	The software shall...

5.2 Audit Trail

List the activities recorded in the application's audit trail. For each activity, list the data recorded.

[Req #]	Title
Req #	The software shall...
Req #	The software shall...
Req #	The software shall...

5.3 Availability

State the time periods during which the system must be available to users, for example, "The system must be available to users Monday through Friday between 06:00 and 18:00 GMT".

If the application will be available in several time zones, state their earliest start and latest stop times. Consider daylight savings time. Identify peak times, i.e. when system availability is most important.

[Req #]	Title
Req #	The software shall...
Req #	The software shall...
Req #	The software shall...

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Capacity Limits

Set the system's capacity requirements in relation to the maximum numbers of transactions, or users, and other quantifiable information. List the required capacities and expected of data in business terms.

Title
The software shall...
The software shall...
The software shall...

Data Retention

Set length of time data must be retained and requirements for its archival and on. For example, "The system shall retain information for 10 years". Identify different data: system documentation, audit records, and database records.

Title
The software shall...
The software shall...
The software shall...

Operational Requirements

Operational requirements and contingencies for areas such as failure modes, start-up or down, maintenance periods, error and recovery handling.

Title
The software shall...
The software shall...
The software shall...

Performance

Specific performance requirements for the system and subsystems. Provide details of units such as, the number of events that must be processed, response times, maximum area to be stored, number of inputs and outputs connected, number of transactions to read in a specified time.

[Req #]	Title
Req #	The software shall...

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Sap: How to Write a Report Functional Specification Linda R. Timms, 2012-05-22 Author Linda Timms goes beyond the standard consulting guide to bring you constructive reliable advice for delivering effective complete professional functional specs on time Filled with plain English real world examples hints and tips SAP How to Write a Report Functional Specification provides the secrets you need to make a daunting task achievable Whether you are a SAP project team member seconded from the business unsure where to start with documenting business requirements a support analyst dealing with change requests and new requirements an offshore analyst consultant wanting to up your game get recognition for top quality work and stand out from the crowd anyone fresh out of a SAP academy or training course wanting to transition smoothly into a valuable project team member a graduate with one of the big management consulting firms wanting focussed reliable advice to help build your consulting career a junior consultant wanting to make a name for yourself as a professional productive good SAP resource an experienced consultant wanting to refresh your knowledge and maybe kick some bad habits a business analyst looking to move into the SAP arena a manager or team lead tasked with reviewing and signing off functional specs a project manager wanting to bring in best practices a technical analyst wanting to understand the functional side of SAP requirements SAP How to Write a Report Functional Specification is a comprehensive guide including a free downloadable functional specification template that will have you producing polished high caliber valuable report specifications in no time

Implementing Electronic Document and Record Management Systems Azad Adam, 2007-08-24 The global shift toward delivering services online requires organizations to evolve from using traditional paper files and storage to more modern electronic methods There has however been very little information on just how to navigate this change until now *Implementing Electronic Document and Record Management Systems* explains how to efficiently

Publications Catalog United States. Internal Revenue Service, 1984 **Practical Batch Process Management** Mike Barker, Jawahar Rawtani, 2004-11-18 Historically batch control systems were designed individually to match a specific arrangement of plant equipment They lacked the ability to convert to new products without having to modify the control systems and did not lend themselves to integration with manufacturing management systems *Practical Batch Management Systems* explains how to utilize the building blocks and arrange the structures of modern batch management systems to produce flexible schemes suitable for automated batch management with the capability to be reconfigured to use the same plant equipment in different combinations It introduces current best practice in the automation of batch processes including the drive for integration with MES Manufacturing Execution System and ERP Enterprise Resource Planning products from major IT vendors References and examples are drawn from DCS PLC batch control products currently on the market Implement modern batch management systems that are flexible and easily reconfigured Integrate batch management with other manufacturing systems including MES and ERP Increase productivity through industry best practice

Managing the Documentation Maze Janet Gough, David Nettleton, 2010-03-16 The accessible easy to follow guide that demystifies documentation management When it comes to receiving documentation to confirm good science U S and international regulators place high demands on the healthcare industry As a result companies developing and manufacturing therapeutic products must implement a strategy that allows them to properly manage their records and documents since they must comply with rigorous standards and be available for regulatory review or inspection at a moment s notice Written in a user friendly Q A style for quick reference Managing the Documentation Maze provides answers to 750 questions the authors encounter frequently in their roles as consultants and trainers In simple terms this handy guide breaks down the key components that facilitate successful document management and shows why it needs to be a core discipline in the industry with information on Compliance with regulations in pharmaceutical biological and device record keeping Electronic systems hybrid systems and the entire scope of documentation that companies must manage How to write and edit documents that meet regulatory compliance Making the transition to an electronic system including how to validate and document the process Anyone responsible for managing documents in the health field will find this book to be a trusted partner in unraveling the bureaucratic web of confusion while it initiates a plan on how to put an effective lasting system in place one that will stand up to any type of scrutiny

Basics of Pharmaceutical Manufacturing and Quality Operations Erfan Syed Asif, Shahid Bader Usmani, 2024-03-14 This book provides guidance on how to meet the requirements of the pharmaceutical industry as a beginner It includes procedures for production and packaging batch auditing as well as all quality measures used in the pharmaceutical industry This book also provides questions and answers with each chapter for institutes and trainers providing basic training to the new graduates and new comers to the industry Basics of Pharmaceutical Manufacturing and Quality Operations A Comprehensive Guide is primarily written for anyone in the pharmaceutical industry interested in development and manufacturing of active pharmaceutical ingredient API and finished pharmaceutical manufacturers in both sterile and non sterile areas The book is a simple concise and easy to use reference tool covering basic quality concepts required by the pharmaceutical educational institutions and professional certification bodies It describes details of all GXP activities that are directly related to Quality Safety and Efficacy of the products manufactured under the umbrella of Quality Operations common testing methods which are used in any modern industry Requirements of Validation and Qualification of equipment facilities and processes integral segments of Drug product manufacturing storage and distribution practices The material provides stepwise guidance on how to evaluate audit qualify and approve a pharmaceutical product to enhance the GMP within the industry The book is written with the idea of providing basic knowledge to undergraduate students who are preparing to enter the industry at the end of their graduation The book would also be beneficial for institutions conducting pharmaceutical technology study courses in terms of GMP and GLP applications Features Provides readers and front line health care product manufacturers all the information they need to

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Effective Prototyping for Software Makers Jonathan Arnowitz, Michael Arent, Nevin Berger, 2010-07-19 Effective Prototyping for Software Makers is a practical informative resource that will help anyone whether or not one has artistic talent access to special tools or programming ability to use good prototyping style methods and tools to build prototypes and manage for effective prototyping This book features a prototyping process with guidelines templates and worksheets overviews and step by step guides for nine common

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